



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL
REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

**CLINICAL ELECTRONIC STRUCTURED HARMONISED
PROTOCOL
(CESHARP)**

M11

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ICH M11 Guideline

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ICH HARMONISED GUIDELINE
STRUCTURE AND CONTENT OF A CLINICAL PROTOCOL
M11
ICH Consensus Guideline

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1 **1. INTRODUCTION**

2 **1.1 Background**

3 The clinical protocol describes the processes and procedures directing the conduct and analysis of
4 a clinical trial of medicinal product(s) in humans. To date, no internationally adopted harmonised
5 standard has been established for the format and content of the clinical protocol to support
6 consistency across sponsors and for the electronic exchange of protocol information.

7 Variability in format and core content among sponsors contributes to inefficiencies and difficulties
8 in searching, reviewing, and assessing clinical trial protocols. Use of the clinical trial protocol
9 template aids the sponsor or sponsor-investigator in the development of a protocol that is complete,
10 free from ambiguity, well organised, and aligned with quality by design principles as set forth in
11 other ICH guidelines. By conveying information consistently and in the same location across
12 clinical trial protocols, a protocol template is intended to provide value to parties that include
13 sponsors, investigators, clinical site personnel, trial participants, ethics committees, and regulators.

14 A technical specification presenting the business requirements and common structured protocol
15 content components and an open, non-proprietary standard for electronic exchange enables
16 development of interoperable electronic tools to facilitate exchange, review, and execution of
17 protocols.

18 **1.2 Purpose**

19 The purpose of this guideline is to describe the general protocol design principles and approach
20 used to develop the separate associated documents, the ICH M11 Clinical Electronic Structured
21 Harmonised Protocol Template [Template] and the Technical Specification that are acceptable to
22 all regulatory authorities of the ICH regions. The Template presents the format and structure of the
23 protocol, including the table of contents, common headers, and contents. The Technical
24 Specification presents the conformance, cardinality, and other technical attributes that enable the
25 interoperable electronic exchange of protocol content.

26 Conformance with this Template and Technical Specification should ensure that protocols are
27 provided in a harmonised data exchange format acceptable to the regulatory authorities. The
28 Template and Technical Specification have been developed with built-in flexibility and are

29 versioned documents. As clinical protocol requirements evolve and technology advances, they may
30 be revised subject to a change control process.

31 **1.3 Scope**

32 The Template and Technical Specification documents supported by this guideline are intended to
33 assist stakeholders (those who use and exchange protocol information, including sponsors,
34 investigators, institutional review boards / ethics committees and regulators in the development,
35 amendment, review, conduct, and closeout of a clinical trial). The Template and Technical
36 Specification are applicable to interventional clinical trials of medicinal products across all phases
37 and therapeutic areas of clinical research. Interventional trials may include but are not limited to
38 human pharmacology, exploratory, confirmatory, and post-approval studies (see ICH E8(R1)
39 General Considerations for Clinical Studies). The term “medicinal product” in this guideline, and
40 the term “trial intervention” in the protocol Template refer to any therapeutic, prophylactic, or
41 diagnostic agent including pharmaceuticals, biologics, vaccines, cell or gene therapy products
42 (when applicable), as well as drug-device combination products when registered as a drug.

43 Neither this Guideline nor the Template or Technical Specification are intended to specify
44 processes related to development and maintenance of a protocol. They do not supersede or negate
45 other guidelines that establish requirements for protocol content. They neither provide instruction
46 on either the development of a well-designed trial nor do they characterise a well-crafted final
47 protocol. Rather, the ICH M11 Guideline, Template, and Technical Specification establish
48 common instructions for placement of content, as reflected in other prevailing guidelines, as well
49 as the technical attributes for interoperable electronic exchange of that content.

50 **2. GENERAL DESIGN PRINCIPLES**

51 **2.1 Clinical Electronic Structured Harmonised Protocol - Template**

52 The Template was designed based on general principles that would support a harmonised standard
53 protocol to facilitate consistency and efficiency in the development, amendment, review, conduct
54 and closeout of a clinical trial and the exchange of protocol information. Specifically, the principles
55 include:

- 56 • **Build common core content** - The Template design represents a core set of information
57 for a clinical trial of any medicinal product(s).

- 58 • **Serve the needs of stakeholders** - The Template's structure and content provide a
59 framework for relevant stakeholders to develop, review and use protocols that consistently
60 and unambiguously include a uniform table of contents, common section headers and
61 content, as well as common terminologies.
- 62 • **Define content for electronic exchange** - The protocol content can be electronically
63 exchanged among parties, including sponsors and regulators, using current (for example,
64 electronic common technical document) and other future technologies.
- 65 • **Design for content re-use** - The clinical protocol is a rich source of information that can
66 be re-used as part of the clinical trial management and review process, and, for example,
67 published on clinical trial registries to promote clinical trial transparency and used in
68 standardised clinical trial data capture.
- 69 • **Maintain flexibility** - The Template incorporates both recommended and optional text and
70 data fields to maintain flexibility. Higher-level heading structure is conserved, while lower
71 level sections can be added, removed, or modified as needed.

72 The Template should be used in conjunction with other ICH Guidelines relevant to the conduct of
73 clinical trials.

74 **2.2 Clinical Electronic Structured Harmonised Protocol - Technical Specification**

75 The Technical Specification includes detailed descriptions of the structured content components
76 (for example, specific data fields and blocks of text-based content), along with other defining
77 attributes and business rules as established in the Template.

78 The Technical Specification is based on the following design principles:

- 79 • Promote structured common core content
- 80 • Define content specifications for electronic exchange
- 81 • Develop a data model based on specifications
- 82 • Focus on relevant content use and re-use
- 83 • Use an open, non-proprietary exchange message standard
- 84 • Maintain flexibility for technical innovation and region-specific use

85

86

87 **3. TEMPLATE CONVENTIONS AND DESIGN**

88 The Template must obviously enable a final protocol that meets the needs of its diverse audience,
89 which include investigators, and site staff, regulatory reviewers, and sponsor personnel. To
90 facilitate efficient and accurate execution, chief consideration was given to the needs of
91 investigators and site staff. Accordingly:

- 92 • The Template is designed with the most vital information for execution (for example,
93 Synopsis, Schema, Schedule of Activities) near the front.
- 94 • The Template is organised in a Main Body/Appendix framework, in which trial-specific
95 information is in the Main Body, while reference details and more general (non-trial-
96 specific) information is in the Appendix. This organisational construct was adopted merely
97 for its utility during execution.
- 98 • Content in the Appendix carries equal weight and rigor as the content in the Main Body.
- 99 • Unnecessary repetition is eliminated wherever possible.